Interview Summary

Applicants and Applicants' representatives gratefully acknowledge the participation of Examiners Gabel and Li in the telephonic interview held November 4, 2002. A brief summary of matters discussed and resolved during the interview is provided herein below.

The indefiniteness rejection of claim 2 was discussed during the interview. Applicants proposed an amendment to step (c) of claim 2, and Examiners Gabel and Li indicated that the amendment, which is set forth herein above, renders the claim definite.

The rejection of claims 1 to 4 under 35 U.S.C. § 102(e) also was discussed during the telephonic interview. Examiners Gabel and Li indicated that this rejection would be removed in view of the distinctions between the claimed invention and the description in the cited reference (U.S. Patent No. 6,033,864 to Braun et al.). Examiners Gabel and Li also indicated that the rejection under 35 U.S.C. § 103(a) over U.S. Patent No. 6,033,864, in view of U.S. Patent No. 5,932,429 to Targan et al., would be removed in view of non-obvious distinctions between the claimed invention and the description in the cited patents.

Regarding the Amendments

As discussed above, step (c) of claim 2 has been amended to indicate that the complex is contacted with a

"labeled" anti-IgA antibody. Support for the amendment to claim 2 can be found throughout the specification, for example, at page 37, lines 23-26, which indicates that an anti-IgA antibody can be a labeled antibody, such as a goat anti-human IgA antibody conjugated to alkaline phosphatase. The amendment is further supported in the specification, for example, at page 39, lines 12-16, which discloses labeled secondary antibodies such as fluorescein-labeled secondary antibodies. Step (d) of claim 2 has been amended to indicate that the presence "or absence" of labeled complex is detected. The amendment to step (d), which conforms with the "presence or absence" language in the concluding phrase of the claim, corrects an obvious error and does not add new matter.

As set forth above, the amendments to claim 2 are supported by the specification as originally filed and do not add new matter. Applicants therefore respectfully request entry of the amendments.

Attached hereto as Appendix A is a marked up version of the amended claim showing specific text changes made to claim 2 using underlining to indicate text added and brackets to indicate text deleted.

Regarding the Withdrawn Claims

As noted above, claims 8 to 11 have been withdrawn from examination as the result of a Restriction Requirement. Applicants' representatives have traversed the Restriction

Requirement and further discussed the requirement with the Examiner in an earlier telephonic interview. Applicants maintain that, while claim 8 and independent claim 10 each recite determining the presence or absence of other antibodies, these claims also require determining the presence or absence of IgA anti-OmpC antibodies as in elected claims 1 to 7. Therefore, these claims, as well as dependent claims 9 and 11, should be examined together with claims 1 to 7.

For the reasons set forth above, it is respectfully requested that claims 8 to 11 be rejoined with the subject matter presently under examination. If this subject matter is not to be rejoined, Applicants' representatives respectfully request that the Examiner call to discuss this issue further.

Regarding the rejection of claims 2 to 7 under 35 U.S.C. § 112, second paragraph

The rejection of claims 2 to 7 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. The Office Action alleges that claim 2 is incomplete for omitting essential elements and that it is unclear how detection would be performed in the absence of a label.

While maintaining that claim 2 is clear and definite to the skilled person as written, Applicants have amended the claim in order to further prosecution to recite a "labeled" anti-IgA antibody and to make the "presence or absence" language consistent in step (d). In the telephonic interview summarized

above, Examiners Gabel and Li indicated that the amendment to "labeled anti-IgA" renders claim 2 definite. Applicants therefore respectfully request removal of the rejection of claims 2 to 7 under the second paragraph of 35 U.S.C. § 112.

Regarding the rejection of claims 1 to 4 under 35 U.S.C. § 102(e) over Braun et al.

The rejection of claims 1 to 4 under 35 U.S.C. § 102(e), as allegedly anticipated by U.S. Patent No. 6,033,864 to Braun et al., respectfully is traversed. While Braun et al. appear to describe the use of a porin antigen for diagnosis of ulcerative colitis, the Office Action points to a statement indicating that the subject to be diagnosed can have one or more symptoms of ulcerative colitis or Crohn's disease and asserts that methods of diagnosing Crohn's disease by determining the presence of anti-OmpC antibodies are therefore described in the cited patent.

As was discussed during the telephonic interview held November 4, 2002, claims 1 to 4 are directed to methods of diagnosing Crohn's disease and recite that the presence of IgA anti-OmpC antibodies indicates that the subject has Crohn's disease. In contrast, the description in U.S. Patent No. 6,033,864 relates to diagnosing ulcerative colitis. Applicants respectfully reiterate that Crohn's disease and ulcerative colitis are distinct syndromes, although both are categorized as inflammatory bowel diseases.

Furthermore, the fact that a patient to be diagnosed can have one or more symptoms of Crohn's disease is not the same as diagnosing a patient with Crohn's disease. Crohn's disease and ulcerative colitis are distinct disorders with often similar common outward symptoms, such as abdominal pain, diarrhea and fever. Although such symptoms can suggest the presence of an inflammatory bowel disease, they are insufficient to indicate which disease, if either, is present in a particular subject. This point is reflected in statements in U.S. Patent No. 6,033,864 that the methods of diagnosing ulcerative colitis involve "obtaining a sample from a subject suspected of having inflammatory bowel disease," and that such a subject can have "one or more symptoms of ulcerative colitis or Crohn's disease." In brief, the above quotations from U.S. Patent No. 6,033,864 merely indicate that a subject tested using the described diagnostic method for ulcerative colitis can have a symptom of either inflammatory bowel disease, but do not indicate that U.S. Patent No. 6,033,864 describes a method of diagnosing Crohn's disease.

Because the cited patent relates to ulcerative colitis and does not describe a method of diagnosing Crohn's disease, claims 1 to 4 are novel over U.S. Patent No. 6,033,864. Accordingly, Applicants respectfully request that the rejection of claims 1 to 4 under 35 U.S.C. § 102(e) be removed.

Regarding the rejection of claims 5 to 7 under 35 U.S.C. § 103 over U.S. Patent No. 6,033,864 in view of Targan et al.

The rejection of claims 5 to 7 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,033,864, in view of U.S. Patent No. 5,932,429 to Targan et al, respectfully is traversed. The Office Action asserts that U.S. Patent No. 5,932,429 describes methods of stratifying Crohn's disease using ASCA and that this description, combined with the teaching of U.S. Patent No. 6,033,864, renders the claimed methods obvious.

Applicants respectfully submit that the combination of cited references does not teach or suggest a method for diagnosing Crohn's disease by determining the presence or absence of IgA anti-OmpC antibodies. On the contrary, the combined references describe (a) a method for diagnosing ulcerative colitis by detecting the presence of porin antigen antibodies, such as anti-OmpC antibodies, as described in U.S. Patent No. 6,033,864 and (b) a method for diagnosing clinical subtypes of Crohn's disease by detecting the presence of perinuclear anti-neutrophil antibodies (pANCA) or an anti-*Saccharomyces cerevisiae* antibodies, as described in U.S. Patent No. 5,932,429. However, the cited references, neither alone nor together, teach or suggest detecting anti-OmpC antibodies for diagnosis of Crohn's disease. Absent such a teaching or suggestion and in accordance with the telephonic interview held November 4, 2002, Applicants respectfully submit that claims 5 to 7 are unobvious over the

cited references and, accordingly, request that the rejection under 35 U.S.C. § 103(a) be removed.

CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned agent or Cathryn Campbell.

Respectfully submitted,

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APPENDIX A

Marked-Up Claim Amendment

2. (Three Times Amended) A method of diagnosing Crohn's disease in a subject, comprising the steps of:

(a) obtaining a sample from a subject suspected of having inflammatory bowel disease;

(b) contacting the sample with an OmpC antigen, or reactive fragment thereof, under conditions suitable to form a complex of the OmpC antigen, or reactive fragment thereof, and IgA antibody to the OmpC antigen;

(c) contacting said complex with **[an]** **a labeled** anti-IgA antibody to form a labeled complex; and

(d) detecting **the presence or absence of** said labeled complex, thereby determining the presence or absence of IgA anti-OmpC antibodies,

where the presence of said IgA anti-OmpC antibodies in said subject indicates that said subject has Crohn's disease.